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Mindfulness-Based Stress Reduction for the Treatment of Irritable Bowel Syndrome Symptoms: A Randomized Wait-list Controlled Trial

Kristin A. Zernicke · Tavis S. Campbell · Philip K. Blustein · Tak S. Fung · Jillian A. Johnson · Simon L. Bacon · Linda E. Carlson

Abstract
Background Irritable bowel syndrome (IBS) is a functional disorder of the lower gastrointestinal (GI) tract affected by stress, which may benefit from a biopsychosocial treatment approach such as mindfulness-based stress reduction (MBSR).
Purpose A treatment as usual (TAU) wait-list controlled trial was conducted in Calgary, Canada to investigate the impact of MBSR on IBS symptoms. It was hypothesized that MBSR patients would experience greater reduction in overall IBS symptom severity and self-reported symptoms of stress relative to control patients.
Method Ninety patients diagnosed with IBS using the Rome III criteria were randomized to either an immediate MBSR program (n=43) or to wait for the next available program (n=47). Patients completed IBS symptom severity, stress, mood, quality of life (QOL), and spirituality scales pre- and post-intervention or waiting period and at 6-month follow-up. Intent-to-treat linear mixed model analyses for repeated measures were conducted, followed by completers analyses.
Results While both groups exhibited a decrease in IBS symptom severity scores over time, the improvement in the MBSR group was greater than the controls and was clinically meaningful, with symptom severity decreasing from constantly to occasionally present. Pre- to post-intervention dropout rates of 44 and 23 % for the MBSR and control groups, respectively, were observed. At 6-month follow-up, the MBSR group maintained a clinically meaningful improvement in overall IBS symptoms compared to the wait-list group, who also improved marginally, resulting in no statistically significant differences between groups at follow-up. Improvements in overall mood, QOL, and spirituality were observed for both groups over time.
Conclusions The results of this trial provide preliminary evidence for the feasibility and efficacy of a mindfulness intervention for the reduction of IBS symptom severity and symptoms of stress and the maintenance of these improvements at 6 months post-intervention. Attention and self-monitoring and/or anticipation of MBSR participation may account for smaller improvements observed in TAU patients.

Keywords Mindfulness-based stress reduction · Irritable bowel syndrome · Stress · Mood · Meditation · Yoga

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Introduction

Irritable bowel syndrome (IBS) is a functional disorder of the lower gastrointestinal (GI) tract defined by the presence

of chronic or recurring symptoms that include abdominal pain, flatulence, bloating, and altered bowel habits [1]. IBS is classified as a functional GI disorder, and hence, there are no known biochemical, structural, or physiological abnormalities that consistently characterize it. Often, a diagnosis of IBS is made when other GI diseases, including inflammatory bowel disease (e.g., Crohn's disease or ulcerative colitis), lactose or gluten intolerance, and intestinal parasites have been ruled out [2]. The prevalence of IBS in Western populations is estimated to be between 5 and 20 % [3–6] and it affects approximately 12 % of Canadian adults (2.8 million) [7]. IBS accounts for 30–50 % of referrals to GI specialists [8, 9] and tends to follow a chronic relapsing and remitting course [10, 11].

A theory proposed by Burnett and Drossman suggests that chronic GI symptoms are generated by a combination of intestinal, motor, sensory, and central nervous system activity termed the "brain–gut axis" [12]. The mechanism for these associations provides a bidirectional relation between sensation in the intestines and intestinal motor function [12–14]. Cognitive information and external stressors have, through neural connections, the ability to affect GI sensation, motility, and secretion [15]. Increased muscle contractions and pain can also increase psychological distress through amplified cognitive interpretations of these sensations [12].

The physiology of the digestive tract, as well as the subjective experience of symptoms, health behaviors, and treatment outcomes, is affected by stress [16–18]. Stress and emotions may trigger neuroimmune/neuroendocrine reactions via the brain–gut axis, subsequently influencing GI, endocrine, and immune function [18, 19]. In both retrospective and prospective studies, chronic stress [20–23], acute stress [24, 25], and increased stress perception have been shown to exacerbate IBS symptomatology [23]. Given the increased stress response associated with viscerally related events, poor or inappropriate coping responses to GI-related events, psychosocial adjustment to illness, and limited success of current medical treatments, psychological treatments have been investigated to address symptoms of IBS.

Psychological treatments, such as cognitive behavioral therapy and hypnosis, have shown promising results, pointing toward the need to incorporate the biopsychosocial perspective into the treatment of IBS symptoms [11]. Preliminary evidence supports cognitive behavioral therapy, dynamic psychotherapy, and hypnotherapy as having therapeutic benefits such as global IBS symptom and abdominal pain reduction greater than usual care; however, only a subset of patients respond and the potential mechanisms for such psychological therapies are not fully understood [26]. Therefore, alternative psychological therapies for IBS warrant investigation, and mindfulness-based stress reduction (MBSR) could, through hypothesized mechanisms, be an alternative treatment for this specific population.

Mindfulness-Based Stress Reduction

MBSR is a group psychosocial intervention, incorporating a biopsychosocial orientation, consisting of mindfulness meditation practice and gentle hatha yoga stretches that has been applied within chronically ill populations, with one goal of reducing stress and disease symptoms [27]. MBSR has its roots in contemplative spiritual traditions in which mindfulness, the cultivation of conscious awareness in the present moment in an open and nonjudgmental manner, is actively practiced [27]. The application of mindfulness-based concepts and techniques is intended to target unhelpful psychosocial processes such as rumination, worry, and poor emotion regulation, potentially leading to improved symptoms, physiological processes, and quality of life (QOL) [28, 29]. MBSR intends to cultivate the ability to develop actively sustained attention to mental content, which may gradually give rise during nonevaluative observation to a greater understanding of perceptions, creating a more accurate representation of one's own mental responses to external and internal stimuli. This awareness may facilitate enhanced emotional processing and coping regarding the effects of chronic illness and stress and improved self-efficacy and sense of control [27, 30].

Mindfulness-Based Stress Reduction for IBS

Meditation programs specifically for the treatment of IBS symptoms are gaining research attention. It is hypothesized that the practice of meditation and ancillary techniques could help patients diagnosed with IBS cope with their disease by providing a means of monitoring and regulating their own arousal, allowing them to gain awareness and evaluate problems with greater emotional stability and by providing an active role in pursuing personal health goals [28]. The focused attention characteristic of mindfulness meditation may enhance a sense of participatory agency during the program and may result in the reduction of stress-related emotional and cognitive factors contributing to the exacerbation of IBS symptoms.

Kearney et al. [31] conducted a prospective nonrandomized trial investigating an MBSR program for 93 patients diagnosed with IBS using the Rome III criteria. Assessment measures at 2- and 6-month follow-up revealed that participation in the MBSR program was associated with improvement in IBS-related QOL and GI-specific anxiety, but not with IBS-specific symptom severity [31]. Due to the promising results, the authors called for randomized controlled trials to investigate the role of MBSR for IBS symptom severity. Gaylord and colleagues subsequently randomized 75 women to one of two 8-week group interventions (mindfulness or social support) and reported clinically significant reductions in IBS symptom severity for the mindfulness

group following the intervention and at 3-month follow-up compared to the social support group [32]. No significant differences were reported between the two groups for psychological distress, QOL, or visceral anxiety immediately post-intervention; however, the mindfulness group showed significant improvements in these measures at 3-month follow-up compared to the support condition [32].

The present investigation furthers the literature by investigating the efficacy of an MBSR program in reducing symptoms of stress and improving psychological well-being as well as IBS symptoms in a sample of men and women who met the Rome III criteria, both immediately following the intervention and at 6-month follow-up. Given the chronic and fluctuating course of IBS, a 6-month follow-up period seems warranted to better investigate the longer-term effects of an MBSR program. Specifically, the present investigation utilized a randomized treatment as usual (TAU) waitlist controlled trial design to examine the impact of an 8-week MBSR program on the physical symptoms of IBS and stress symptoms, as well as several psychological aspects of well-being including QOL, mood, and spirituality immediately after the program and 6 months later. It was hypothesized that patients who participated in the MBSR program would experience: (1) greater reductions in IBS symptom severity; (2) greater reduction in non-GI symptoms of stress and mood disturbance and improved QOL compared to a TAU wait-list control; and that (3) reduction in symptoms would be maintained at the 6-month follow-up.

Methods

Sample

Ethics approval was obtained from the Office of Medical Bioethics, Faculty of Medicine, University of Calgary. Men and women who received a diagnosis of IBS by a gastroenterologist in Calgary, Alberta, Canada were identified through medical chart review and recruited from multiple gastroenterologists' offices from summer 2007 to fall 2010 via invitation phone calls. In addition, gastroenterologists within the community were provided with pamphlets and posters to refer newly diagnosed and existing patients to the study. Self-referred patients were first screened by a gastroenterologist. Patients were eligible for the study if they met the following inclusion criteria: (1) age 18 years or older; (2) English-speaking; and (3) had a diagnosis of IBS confirmed by a gastroenterologist using the standard Rome III criteria [13]. Exclusion criteria for this study included: (1) a concurrent self-reported diagnosis of a DSM-IV axis I mood, anxiety, or psychotic disorder; (2) current use of antipsychotics; or (3) past participation in an MBSR group. Medical or psychiatric conditions and medications were assessed during the first data collection session using a medical history questionnaire designed for this study and, if required, followed up for diagnostic clarity by the clinical psychologist principal investigator (LEC).

During screening, patients were asked to self-report whether they had recently started or changed any medications within the last 3 months. In order to ensure stability of medication over the course of the study, if there had been a change in medication, patients were asked to wait 3 months before being enrolled in the next cohort for randomization and not to change regimens or dosages for the duration of the study. Prior to the intervention, patients completed informed consent, and baseline study measures were obtained. Consenting patients were randomized to either the immediate MBSR intervention or to the TAU control group, which received the MBSR program after the 6-month follow-up period. Randomization was completed with a computer-based two-digit random number generation program.

Psychological Questionnaire Measures

Demographic and Medical History Questionnaires

A demographic questionnaire assessing age, sex, socioeconomic status (years of education), and education was administered, as well as a questionnaire assessing medical history, psychiatric history, and current medications.

Health Behaviors Forms

A retrospective self-report questionnaire was administered to assess frequency of alcohol, nicotine, and caffeine consumption (per day, week, or month). Sleep amount and quality (poor, fair, or good), physical activity, and diet (poor, fair, or good) were also assessed. These behaviors have been identified as triggers for IBS symptoms [33].

Meditation Practice

A weekly practice log was included in the MBSR patient booklet. Patients recorded the total minutes spent daily meditating and practicing the skills learned in the classes throughout the MBSR intervention.

IBS Severity Scoring System (IBS-SSS)

The severity scoring system (SSS) is an IBS-specific instrument that is sensitive to change in symptoms over time [34]. The score of the system is based on five items and uses visual analogue scales. The symptom severity score was calculated by summing the five items: pain severity, pain frequency, distension, bowel habit dissatisfaction, and life

interference. Patients were classified as having either mild IBS (75–174), moderate IBS (175–299), or severe IBS (300–500). Scores below 75 indicate remission or normal bowel function. This measure has adequate discriminant validity between controls and patients diagnosed with IBS ($p=0.0001$), as well as between the severity categories measured ($p<0.01$) [34]. In a validation paper to test responsiveness, Francis et al. [34] measured scores of IBS patients both before and after a psychosocial intervention designed to treat IBS symptoms. Patients judged independently by a clinician as "considerably better" after the intervention showed a change score of 50 points, reliably indicating clinical improvement. The instrument has high reproducibility for scores repeated within 24 h and is sensitive to change ($p<0.001$). In this study a change of 50 points was similarly considered clinically meaningful.

Secondary Outcome Measures

Quality of Life (IBS-QOL)

The IBS-QOL measurement is a 34-item instrument developed at the University of Washington [35]. The measure is scored using a five-point Likert scale with scores summed on eight subscales. These subscales are labeled dysphoria, interference with activity, body image, health worry, food avoidance, social reaction, sexual, and relationships. Significant correlations were shown between change scores on the IBS-QOL and other measures of treatment effect (i.e., averaged daily pain/14 days, Sickness Impact Profile total score, and Sickness Impact Profile psychosocial score) [36]. The IBS-QOL measure demonstrated high internal consistency (Cronbach's $\alpha=0.95$) and high reproducibility (ICC=0.86) with average time of 7 days (SD=1). Regarding discriminant validity, number of symptoms ($p<0.05$), self-reported severity of symptoms ($p<0.001$), and functional bowel disorder severity index ($p<0.001$) predicted IBS-QOL scores [35]. Convergent validity confirmed predictions that scores were more closely related to psychological well-being (0.45) than to function (0.36) on this scale [35].

Mood (POMS)

Current mood was measured with the Profile of Mood States (POMS) [37]. This instrument generates scores on six dimensions of mood: tension–anxiety, depression–dejection, anger–hostility, vigor, fatigue, and confusion. It has been widely used in psychiatric and medical populations. The POMS measures state (vs. trait) attributes, which makes it appropriate for repeated measures. Kuder–Richardson internal consistency of the six subscales ranged from 0.84 (confusion) to 0.95 (depression) in two studies, with test–retest stability of 0.65 (vigor) to 0.74 (depression) over a period of 20 days on average. This was consistent with the POMS as a measure of mood states, which were expected to vary over time (nonstable traits), and supported its construct validity [37].

Symptoms of Stress (C-SOSI)

A short form of the Symptoms of Stress Inventory (SOSI) [38], the Calgary Symptoms of Stress Inventory (C-SOSI) [39], was used to measure physical, psychological, and behavioral responses to stressful situations. The questionnaire consists of 56 items and 8 subscales. The C-SOSI has good internal consistency and face validity. Cronbach's α reliabilities for the subscales ranged from 0.80 to 0.95 [39].

Spirituality (FACIT-sp)

Spiritual well-being was measured using the Functional Assessment of Chronic Illness Therapy—Spiritual Well-being (FACIT-sp) Scale [40], a 12-item self-report questionnaire designed for people with chronic illnesses which measures a sense of peace and meaning and purpose in life. In a study of 1,617 subjects with chronic illness (83.1 % were patients with cancer), internal consistency was 0.87 for the total FACIT-sp score. Reliability was also shown in this multiethnic sample [40]. This instrument was included because it has been shown to increase in previous MBSR studies in other medical populations [41].

Intervention

The MBSR intervention was based on the program designed by Kabat-Zinn and colleagues at the Stress Reduction Clinic at the University of Massachusetts Medical Center [27] and detailed elsewhere [41–44]. All sessions were administered by a registered nurse who was also a certified yoga instructor and professionally trained through the University of Massachusetts Medical Center Oasis MBSR training program. She has been teaching MBSR since 2000 and facilitated numerous trials ongoing at the Tom Baker Cancer Centre, Calgary, Canada. This manualized group intervention consisted of eight weekly group sessions 90 min in duration, in addition to a 3-h morning workshop retreat between weeks 6 and 7. Shorter classes and retreat compared to the standard protocol were used for logistical reasons of integrating the research protocol into the ongoing clinical and research programs at the Tom Baker Cancer Centre. Patients were taught meditation techniques and body awareness skills in a didactic classroom format and were encouraged to engage in home practice of meditation and yoga between class sessions. Instructional and experiential modes of learning were used to implement the intervention. General psychoeducation regarding stress and the stress

response was taught. The 3-h retreat allows for an extended practice of a combination of mindfulness skills learned in the program including yoga, sitting meditation, body scan, loving–kindness meditation, and walking meditation. The retreat was conducted in silence for patients and encouraged further delving into the mindfulness practice with an extended period of time for inner reflection and the development of insight.

At the start of the MBSR program, each patient was provided a 52-page booklet and two CDs to aid in home meditation and yoga practice. To measure adherence, the MBSR instructor recorded the number of classes each participant attended, and the patients recorded the total minutes spent daily mediating and practicing yoga on a weekly practice log included in the booklet during the course of the intervention. All practice logs were collected weekly by the instructor during the intervention. While logs collected by the instructor may introduce a social desirability bias, this action was taken to attempt to mitigate the issue of patients attempting to retrospectively, at the end of the 8-week intervention, complete several weeks of logs and report the minutes/activities they had completed several weeks ago. The instructor did not look at or comment on the logs as they were simply put into an envelope each week which went directly to the researcher—patients were aware of this setup, told that it was done so that they would not feel any pressure, and asked to be honest with their logs for the sake of the study. All patients were encouraged in both the treatment and control conditions to continue with their general medical care and IBS-specific care throughout the study, such as attending regularly scheduled appointments with their specific gastroenterologist, and to continue with any of their medications and treatments throughout the study.

Data Analysis

Power analyses were conducted for the current trial using the IBS-SSS validation paper of Francis et al. [34]. Allowing for 20 % attrition, 42 patients per group (n=84) were required to detect a magnitude of change at β=0.80 and α=0.05. All data provided by patients were included in the analyses. Data were tested for normality and homogeneity of variance. To verify that the intervention and control groups were comparable on continuous and categorical demographic variables, IBS symptom severity, and psychological variables at pre-intervention, a series of independent samples t tests and chi-squared tests were conducted. If between-group differences existed at baseline, such differences were adjusted for statistically in subsequent analyses.

In order to evaluate the impact of the MBSR intervention on the primary and secondary outcome measures, linear mixed models for repeated-measures analyses were performed using an intent-to-treat (ITT) principle, so that all patients who provided baseline data were included in the analyses. Post hoc comparisons were conducted to follow-up significant main effects and interactions. Linear mixed models is an appropriate statistical method for longitudinal designs with missing data in clinical trials as it imputes missing data using mathematical models rather than relying on last observation carried forward. A completers analysis was also conducted to compare the ITT linear mixed model results to the data provided by patients who completed five or more classes (more than half the program) due to the significant dropout rates. The completers analysis is reported if it differed from the primary ITT analysis in the "Results" section below. All data analyses were carried out using SAS for Windows version 9.2 (SAS Institute Inc., 2008). Additional analyses were calculated for the IBS-SSS scale, including IBS symptom severity change scores for patients who completed the program to compare results to previously published research, as well as an analysis of clinical response defined and calculated as the number of patients who showed a 50-point improvement on the IBS-SSS.

Results

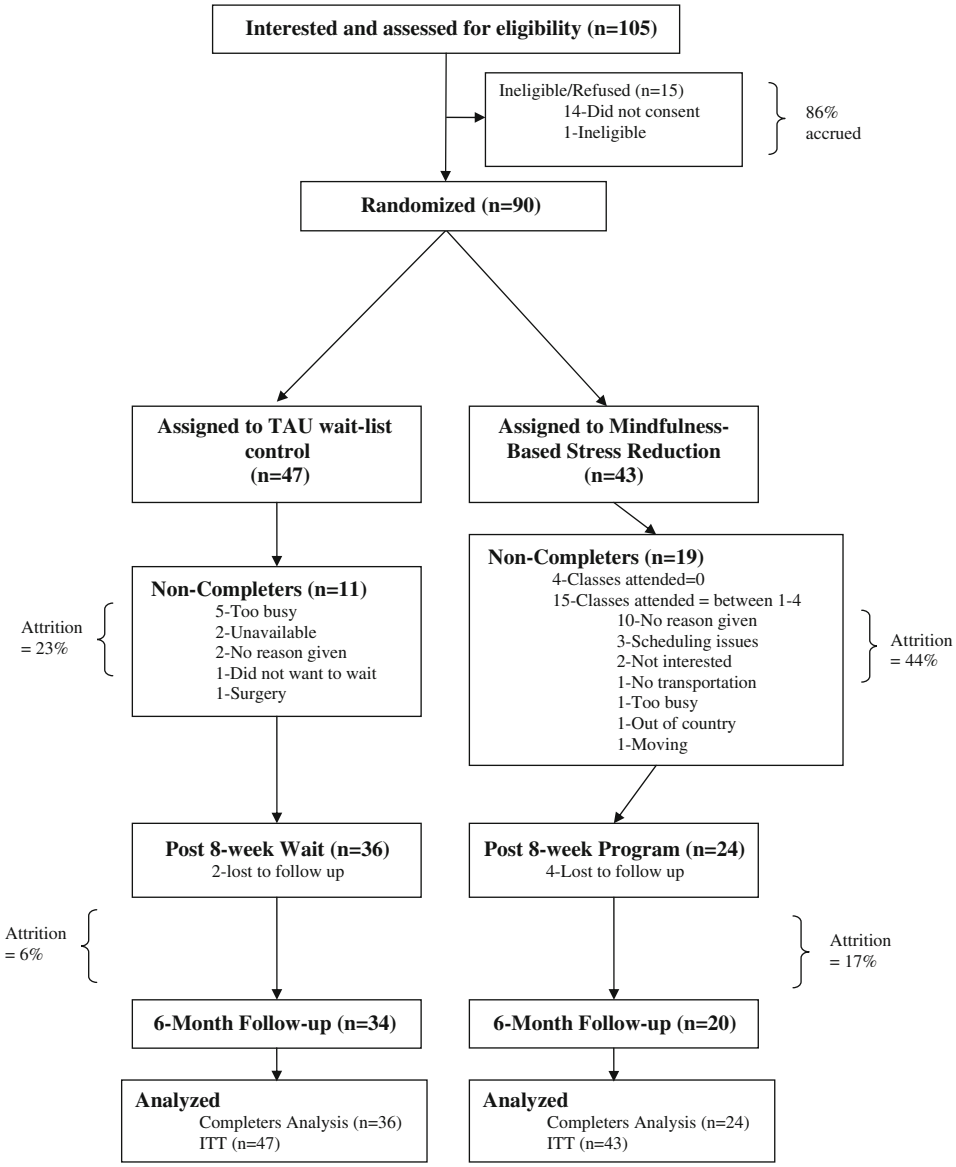
Participant Characteristics

Screening, eligibility, consent, and dropout rates are provided (Fig. 1). One hundred and five eligible patients were assessed. In total, 90 patients completed baseline measures and were then randomized into treatment conditions (immediate n=43, wait-list n=47). Four cohorts were conducted, and within each class, there was a range of 11–19 patients. The majority of patients were women (90 %) and in a coupled relationship (62.2 %). Patients ranged in age from 18 to 77 years with a mean age of 45 years (Table 1).

Attrition and Compliance

Dropout rates for intervention and control groups did not differ significantly, $\chi^2(1,90)=2.03$, $p=0.15$. Of the 43 MBSR patients, 24 completed at least 5 or more classes, and of the 47 patients waiting, 36 completed the waiting period and second questionnaire (Fig. 1). The mean number of MBSR classes attended was six out of nine (including the half-day silent retreat). The mean amount of home meditation and yoga practice, which did not include the weekly class practice or retreat, was 137 min/week. No significant differences were found between those who completed and those who did not complete the study in terms of the measured continuous or categorical demographic variables or baseline IBS symptom severity, QOL, mood, stress, or spirituality scores. All MBSR and control group baseline,

Fig. 1 Flowchart



8-week, and 6-month means and standard deviations for all scales are presented in Table 2.

IBS Symptom Severity (IBS-SSS)

Results of the linear mixed model analyses of IBS symptom severity total scores revealed a time by group interaction, $F(2,106)=3.90$, $p=0.02$, which indicated that the group effect varied with time and vice versa. Testing of simple effects indicated that IBS symptom severity improved ($p<0.0001$) from pre- to post-intervention for the immediate MBSR group, with results maintained at 6-month follow-up ($p=0.17$). This improvement was clinically meaningful with an overall change score >50 points. Of the 24 patients that completed 5 or more classes, 4 of these patients did not complete the post-MBSR intervention (T2) IBS-SSS questionnaire. Therefore, out of 20 patients with full data who completed 5 or more classes, 10 had a clinically significant improvement in symptoms (50 %) post intervention.

For the 47 TAU wait-list group patients that completed the IBS-SSS, 10 out of 47 patients (21 %) had a clinically significant improvement in IBS symptoms. Although the wait-list did not show improvements in symptom severity from baseline to 8-week assessment, symptoms were significantly reduced from baseline to 6-month follow-up; however, this symptom reduction did not meet clinical significance. The MBSR treatment group reported lower symptom severity overall at post-intervention compared to the wait-list group. There was no difference between the two groups at 6-month follow-up (Fig. 2).

Change scores calculated for patients who completed the intervention showed a 30.7 % reduction in IBS symptom severity immediately post-MBSR compared to the controls (5.2 %). The ITT estimate using linear mixed models for

Table 1 Participant demographics

	Mindfulness group (n=43)	Wait-list group (n=47)
Sex		
Female	40 (90.3 %)	41 (87.2 %)
Male	3 (7.0 %)	6 (12.8 %)
Age	45 (SD=12.4)	44 (SD=12.6)
Relationship status		
Single—never married	14 (32.6 %)	12 (25.5 %)
Living with partner—never married	1 (2.3 %)	5 (10.6 %)
Married	22 (51.2 %)	28 (59.6 %)
Divorced or separated	4 (9.3 %)	2 (4.3 %)
Widowed	1 (2.3 %)	–
Not disclosed	1 (2.3 %)	–
Employment status		
Full-time	24 (55.8 %)	31 (66.0 %)
Part-time	9 (20.9 %)	7 (14.9 %)
Unemployed	4 (9.3 %)	5 (10.6 %)
Retired	4 (9.3 %)	2 (4.3 %)
Disability	–	2 (4.3 %)
Not disclosed	2 (4.7 %)	–
Education		
Primary/secondary school	–	1 (2.1 %)
High school graduate	4 (9.3 %)	8 (17.0 %)
Some university/college/tech	9 (20.9 %)	12 (25.5 %)
College/tech degree	11 (25.6 %)	9 (19.1 %)
University degree	11 (25.6 %)	13 (27.7 %)
Masters/postgraduate degree	5 (11.6 %)	3 (6.4 %)
Doctoral degree	1 (2.3 %)	1 (2.1 %)
Not disclosed	2 (4.7 %)	–

repeated measures (included all patients who provided baseline scores) showed a 16.9 % reduction in IBS symptom severity post-MBSR compared to 3.5 % in the controls.

Symptoms of Stress (C-SOSI)

Analyses of the C-SOSI total scores revealed a time by group interaction, $F(2,108)=3.92$, $p=0.02$, which indicated that the group effect varied with time and vice versa. Testing of simple effects indicated that symptoms of stress were reduced ($p<0.0001$) from pre- to post-intervention for the MBSR treatment group, with results maintained at 6-month follow-up ($p=0.08$). However, for patients who completed five or more classes, from post-MBSR to 6-month follow-up, there was a significant rebound effect ($p=0.04$). The wait-list group did not show a reduction in symptoms of stress from baseline to 8-week assessment; however, stress symptoms were significantly reduced from baseline to 6-month follow-up. The treatment group reported fewer overall symptoms of stress at post-intervention relative to the wait-list group. The groups did not differ at 6-month follow-up (Fig. 3).

Profile of Mood States (POMS)

Linear mixed model analyses revealed a main effect of time on patients' total mood disturbance scores, $F(2,109)=8.48$, $p<0.001$. Post hoc analyses indicated that mood scores at 8-week assessment and at 6-month follow-up were lower compared to baseline mood scores regardless of group assignment.

Quality of Life (IBS-QOL)

Results of the linear mixed model analyses on the IBS-QOL total scores revealed main effects of time, $F(2,109)=9.62$, $p<0.001$. Results of follow-up analyses indicated that, regardless of group assignment, total scores for QOL improved at 8-week and 6-month assessment compared to baseline scores.

Spirituality (FACIT-sp)

A main effect of time was observed for the FACIT-sp total score, $F(2,106)=4.96$, $p=0.009$. Post hoc analyses revealed higher total scores at 8-week assessment and at 6-month follow-up when compared to the baseline, regardless of group assignment.

Discussion

The primary aim of this study was to evaluate the impact of an 8-week MBSR program on the physical symptoms of IBS in men and women. Consistent with our primary hypothesis, the MBSR treatment group improved more than the controls on the primary outcome of symptom severity. The change was clinically meaningful and brought symptoms from the severe to moderate range. These improvements were maintained over 6 months. Practically, this would mean a person went from almost constantly having severe and frequently interfering symptoms of pain and/or bowel distension and low satisfaction with their bowel habit in general to only occasionally experiencing these problems. Such a change could conceivably mean the difference between remaining cloistered in the home to being able to participate more in work and social functions. These improvements occurred despite the intervention being a fairly "generic" MBSR program. An MBSR program adapted and more specifically geared toward IBS-specific

Table 2 Means and standard errors and effect sizes for outcome measure total scores for MBSR treatment and control groups

	Mindfulness group, adjusted mean (SD) (n=43)	Wait-list group, adjusted mean (SD) (n=47)	Cohen's d (between groups)
IBS-SSS total score[a,b,*,**]			
Baseline	248.6 (108.9)	249.0 (107.6)	
Posttreatment	169.4 (125.9)	230.0 (117.9)	0.50
6-month follow-up	193.6 (128.5)	213.8 (119.3)	0.16
IBS-QOL total score[b,**]			
Baseline	65.3 (23.6)	61.6 (23.3)	
Posttreatment	75.0 (24.9)	63.1 (23.3)	0.49
6-month follow-up	74.3 (26.9)	66.5 (24.0)	0.31
C-SOSI total score[a,b*,**]			
Baseline	76.7 (34.8)	81.7 (34.3)	
Posttreatment	52.2 (40.7)	75.7 (37.7)	0.60
6-month follow-up	62.1 (41.3)	69.8 (38.4)	0.19
POMS total score[b,**]			
Baseline	48.6 (36.7)	50.1 (36.3)	
Posttreatment	28.5 (45.9)	37.4 (41.8)	0.21
6-month follow-up	31.6 (47.2)	33.5 (42.5)	0.04
FACIT total score[b,**]			
Baseline	27.5 (8.5)	25.9 (8.9)	
Posttreatment	30.5 (10.5)	26.8 (9.6)	0.37
6-month follow-up	30.4 (10.5)	28.3 (9.6)	0.21

*p<0.05; **p<0.01

[a]Interaction effect

[b]Time effect

content may yield greater improvements in IBS symptoms; however, this has yet to be evaluated.

Compared to the only other randomized trial of MBSR for IBS patients [32], these results are similar. Patients who completed the intervention in our study had a 30.7 % reduction in IBS symptom severity immediately post-MBSR compared to the controls (5.2 %). Gaylord et al. showed a 26.4 % reduction on the same scale, compared to 6.2 % for the support group condition [32]. Our more conservative ITT estimate, which included all patients who completed baseline data in the analysis, showed a 16.9 % reduction in IBS symptom severity post-MBSR compared to 3.5 % in the controls. The actual impact of the program likely lies between these two values.

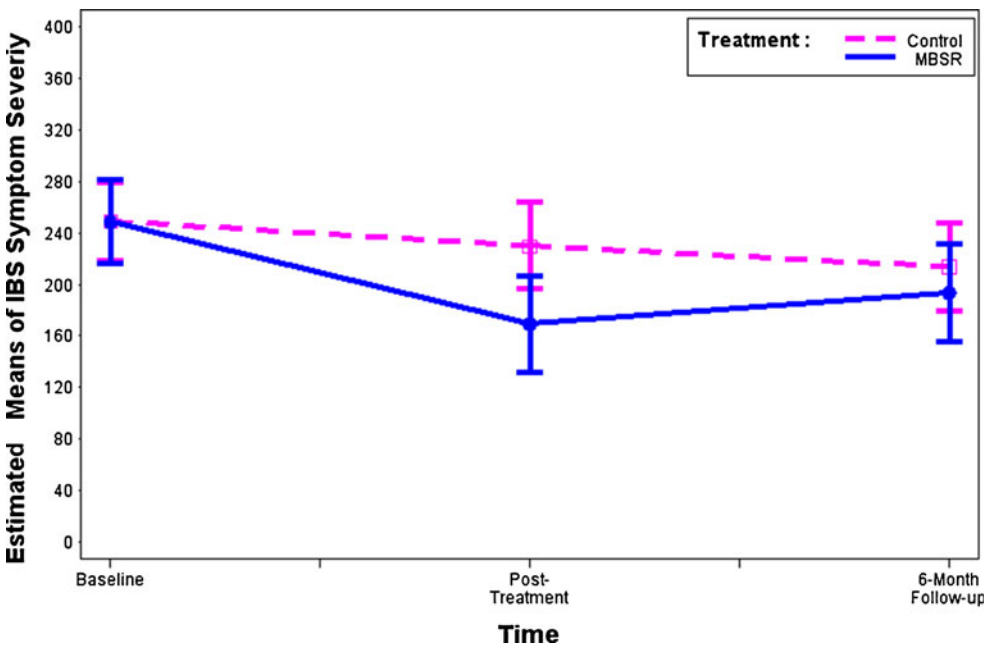


Fig. 2 Impact of MBSR on the IBS-SSS. The line graph represents the association between group status (treatment vs. control) and change in total IBS severity scores across three time periods

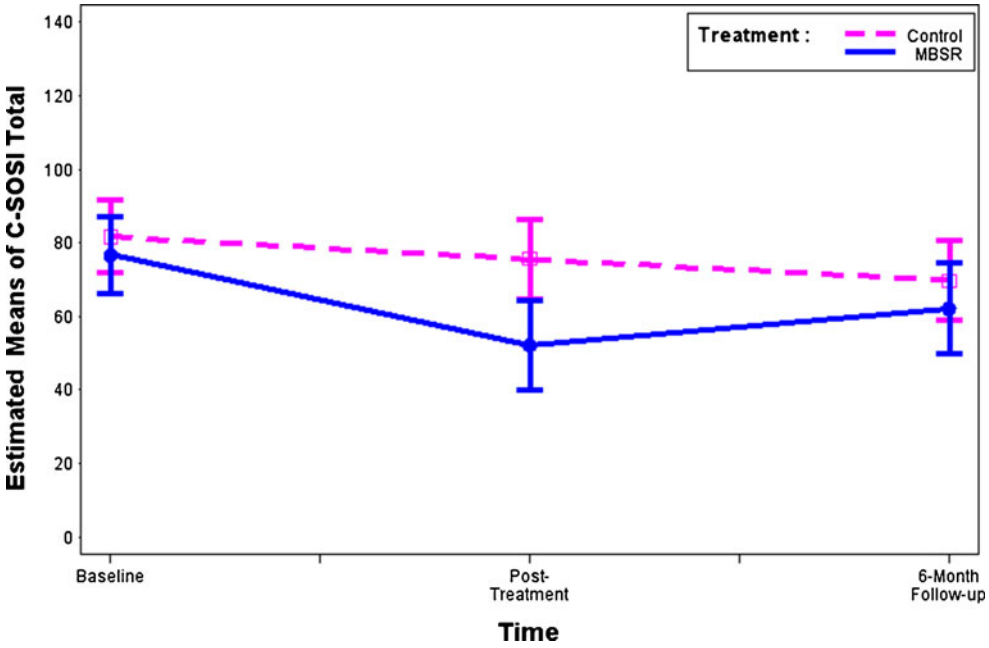


Fig. 3 Impact of MBSR on the C-SOSI total score. The line graph represents the association between group status (treatment vs. control) and change in total symptoms of stress scores across three time periods

Where our methods differed from Gaylord et al. [32] is in following up patients for twice as long post-program and including a wider range of outcome measures across many domains. Interestingly, we saw something of a rebound effect of symptoms in the MBSR group over the follow-up period (Fig. 2), while the control patients continued to improve slowly over time. This suggests that the acute effects of program participation far outstrip the rate of improvement in the absence of intervention, but this rate of improvement is not necessarily sustained over time. Unfortunately, attempts to collect data on adherence to meditation practice over the follow-up period were not successful and we were unable to assess any associations between further changes and home practice. One might assume that those patients who continued to practice meditation over time may maintain the initial program benefits, but we were unable to assess this question.

It might also seem surprising that the control group was improving slowly over time on IBS-specific measures, given the chronic nature of the illness and long time since symptom onset (>1 year). One possible explanation for this may be positive expectations about starting the MBSR program after the waiting period. Follow-up by the research team and continued self-monitoring and support over this period may have also contributed to this improvement.

This trial was the first to specifically measure symptoms of stress in MBSR for IBS patients. As predicted, MBSR patients had decreased overall symptoms of stress compared to the controls immediately after the 8-week program. These results are consistent with MBSR outcomes in a variety of other clinical populations such as anxiety, fibromyalgia, cancer, and hypertension [28, 41, 45–49]. For the first time, this can now be extended to an IBS-specific population. Similar to the previously reported results of IBS symptoms, overall symptoms of stress also continued to improve slowly over time.

While there were specific improvements in IBS and stress symptoms in the MBSR group, both groups improved over time on IBS-specific QOL, mood disturbance, and spirituality. A possible explanation for this is similar to that for specific IBS symptoms, that improvements may be due to nonspecific effects. Symptom monitoring, attention from the research team, and anticipation of a treatment program could lead to appreciable symptomatic relief among control group patients, while attention and group support could be beneficial to those in the treatment group. Consistent with this interpretation, patients diagnosed with IBS respond well to placebo in drug studies, where up to 72 % of those in a placebo condition experience symptom improvement as measured by global symptom ratings [50]. A second possible explanation for overall improvement is that the process of filling out questionnaires leads patients to reflect upon their current thoughts, symptoms, feelings, and behaviors. Self-monitoring is a treatment component of cognitive behavioral therapy for IBS, but the incremental effect of symptom monitoring in a multicomponent treatment has yet to be evaluated.

This study had several strengths and limitations. A significant strength was the randomization of patients to either the MBSR or TAU wait-list condition and the extended 6-month follow-up. The recruitment and randomization process resulted in two groups that were equivalent at baseline on demographics and pre-intervention test scores. A second significant strength of our study is the data analytic procedure which accounts for our high attrition rate. While there were no significant differences in attrition between the MBSR and

control conditions, a substantial number of patients did not complete the full trial, with 44 % in the MBSR group not completing five or more classes. The time commitment and motivation required to attend a class for 8 weeks for 1.5 hours, plus 45 min of meditation and yoga daily were significant. This group of patients was recruited largely by cold calling patients from gastroenterologists' charts; hence, many had been diagnosed many months or years previously, and none were specifically symptomatic or seeking treatment options for stress reduction. Hence, they may not have been highly motivated to complete treatment if they became busier than anticipated, had significant stressors arise, or did not immediately see the value of the intervention.

The current study's results should be considered within the methodological limitations of a preliminary treatment outcome study with a relatively small sample, including the fact that the control group did not receive any placebo intervention which would be considered the gold standard for randomized intervention trials. However, a meta-analysis conducted by Grossman et al. revealed similar effect sizes across many types of MBSR study designs (e.g., controlled vs. observational) and within the controlled study analysis (active control vs. wait-list), which provide support for the specificity of the mindfulness intervention [30].

Patients with self-reported axis I mood and anxiety disorders were excluded in order to produce a clean sample; however, due to the relatively high comorbidity rates of mood and anxiety disorders within the IBS population, this limits the generalizability of our sample. While we did not conduct standardized diagnostic interviews to assess such comorbidities, we asked patients to self-report comorbid disorder diagnoses and also screened patient's medical charts for comorbid diagnostic information. Another limit to generalizability is that over half of the treatment and control groups earned a post-secondary degree within our sample, as well as in the trial of Gaylord et al. [32]. Hence, these results may not apply to less highly educated samples of IBS sufferers.

Future research may further examine the characteristics of the sample that choose to continue with the program, compared to those who dropped out, in order to determine factors that may influence goodness-of-fit between the individual and the intervention. By recruiting individuals interested in taking a class on mindfulness meditation, we obtained a self-selected sample. It is possible that patients interested in enrolling in MBSR or those who chose not to drop out are more interested in self-exploration, meditation, and alternative approaches to health care and may be more psychologically minded. Thus, the results of the study likely only apply to patients who are receptive to the idea of mindfulness, who expect to benefit from the program, or who agree that stress is an issue relating to their irritable bowel symptoms. The latter is substantiated by previous research that indicates that a proportion of IBS sufferers seeking health care are unwilling to consider stress as an operative factor in IBS [36, 51, 52]. We also encountered this opinion in many of the IBS patients who were called for the study but were not interested in participating.

In summary, participation in the MBSR program was associated with a significant reduction in IBS symptom severity and symptoms of stress, compared to the TAU wait-list control condition. Improvements in IBS-related QOL and mood were observed for both the intervention and TAU wait-list. As many studies have linked high symptoms of stress, mood disturbance, and low QOL to adverse health outcomes, the current and previous studies suggest that mindfulness meditation may be an activity that promotes better health. Overall, MBSR is a promising psychosocial intervention for patients suffering with the symptoms of IBS and further randomized controlled trials with active control conditions and longer-term follow-up are needed to determine the effect of such a program for this heterogeneous patient population.

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Conflict of interest None.

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